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Filed : August 1, 2003

REMARKS

Claims 1-10, 12-48, and 50-62 are pending in this application. Claims 1, 17, 20, 36, 39, and 58-62 have been amended. Claims 11 and 49 have been canceled. Support for the amendments is found in the specification and claims as filed. For example, support for the amendment to Claim 1 is found in Fig. 11 and the associated description. Support for the amendments to Claims 29, 39, and 60 can be found, e.g., in paragraphs [0001] and [0006] and the portions of the specification that are dedicated to describing the ability to provide real-time continuous analyte information displayed on the user interface, for example at paragraphs [0332] and [0337]. Support for the amendments to Claims 59 and 61 can be found, e.g., at paragraph [0332].

Claim Objections

Claims 11, 17, 36, 49, 58, and 60 have been objected to. Claims 11 and 58 and Claims 49 and 60 have been objected to for being substantial duplicates of each other. Claims 11 and 49 have been canceled. Claims 17 and 36 have been amended to recite “alerting a user”. In view of the foregoing amendments, Applicants respectfully request withdrawal of the objections.

Claim Rejections - 35 U.S.C. § 102(b)

Claims 1, 4-7, 11, 15-20, 23-26, 30, 34-40, 43-45, and 49-62 have been rejected under 35 U.S.C. §102(b) as anticipated by the Mastrototaro article entitled “The MiniMed Continuous Glucose Monitoring System” (hereinafter “Mastrototaro”). “A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference.” *See, e.g., In re Paulsen*, 31 U.S.P.Q.2d 1671 (Fed. Cir. 1994). Mastrototaro does not disclose every element of Applicants’ claims, and therefore cannot be considered as an anticipating reference under 35 U.S.C. § 102(b).

Pending Claim 1 recites a method for evaluating the quality of a calibration of an analyte sensor comprising “receiving a data stream from an analyte sensor, including one or more sensor data points; receiving reference data from a reference analyte monitor, including two or more reference data points; providing at least two matched data pairs by matching reference analyte data to substantially time corresponding sensor data; forming a calibration set including said at

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least two matching data pairs; creating a conversion function based on said calibration set; *receiving additional sensor data from the analyte sensor, wherein the step of receiving additional sensor data from the analyte sensor is performed after the step of creating a conversion function*; converting sensor data into calibrated data using said conversion function; and evaluating the quality of said calibration set using a data association function" (emphasis added).

Pending Claim 20 recites a system for evaluating the quality of a calibration of an analyte sensor comprising "means for receiving a data stream from an analyte sensor, a plurality of time-spaced sensor data points; means for receiving reference data from a reference analyte monitor, including two or more reference data points; means for providing two or more matched data pairs by matching reference analyte data to substantially time corresponding sensor data; means for forming a calibration set including at least two matched data pairs; means for creating a conversion function based on said calibration set; *means for prospectively converting sensor data into calibrated data using said conversion function*; and means for evaluating the quality of said calibration set based on a data association function" (emphasis added).

Pending Claim 39 recites a computer system for evaluating the quality of a calibration of an analyte sensor comprising "a sensor data receiving module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor; a reference data receiving module that receives reference data from a reference analyte monitor, including two or more reference data points; a data matching module that forms two or more matched data pairs by matching reference data to substantially time corresponding sensor data; a calibration set module that forms a calibration set including at least two matched data pairs; a conversion function module that creates a conversion function using said calibration set; *a sensor data transformation module that prospectively converts sensor data into calibrated data using said conversion function*; and a quality evaluation module that evaluates the quality of said calibration set based on a data association function" (emphasis added).

Pending Claim 58 recites a method for evaluating the quality of a calibration of an analyte sensor comprising "receiving a data stream from an analyte sensor, including one or more sensor data points; receiving reference data from a reference analyte monitor, including two or more reference data points; providing at least two matched data pairs by matching reference analyte

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data to substantially time corresponding sensor data; forming a calibration set including said at least two matching data pairs; creating a conversion function based on said calibration set; *prospectively converting additional sensor data into calibrated data using said conversion function*; and evaluating the quality of said calibration set based on a data association function selected from the group consisting of linear regression, non-linear regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference" (emphasis added).

Pending Claim 59 recites a method for evaluating the quality of a calibration of an analyte sensor comprising "receiving analyte sensor data from an analyte sensor; receiving reference data from a reference analyte monitor; providing at least two matched data pairs by matching reference analyte data to substantially time corresponding sensor data; creating a conversion function based on said at least two matched data pairs; *converting sensor data into substantially real-time analyte values using said conversion function as sensor data is continuously or intermittently received from the sensor*; and providing an output to a user interface responsive to the data association of said at least two matched data pairs" (emphasis added).

Pending Claim 60 recites a computer system for evaluating the quality of a calibration of an analyte sensor comprising "a sensor data module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor; a reference input module that receives reference data from a reference analyte monitor, including two or more reference data points; a processor module that forms two or more matched data pairs by matching reference data to substantially time corresponding sensor data and subsequently forms a calibration set including said two or more matched data pairs; a conversion function module that creates a conversion function using said calibration set; *a sensor data transformation module that prospectively converts additional sensor data into calibrated data using said conversion function*; a quality evaluation module that evaluates the quality of said calibration set based on a data association selected from the group consisting of linear regression, non-linear regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference" (emphasis added).

Pending Claim 61 recites a computer system for evaluating the quality of a calibration of an analyte sensor comprising "a sensor data module that receives analyte sensor data from a

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substantially continuous analyte sensor; a reference input module that receives reference data from a reference analyte monitor; a processor module that forms two or more matched data pairs by matching reference data to substantially time corresponding sensor data; a conversion function module that creates a conversion function using said two or more matched data pairs; *a sensor data transformation module that converts sensor data into substantially real-time analyte values using said conversion function as sensor data is continuously or intermittently received from the sensor*; and a fail-safe module that controls the user interface based on the data association of said two or more matched data pairs" (emphasis added).

Pending Claim 62 recites a method for evaluating the quality of a calibration of a glucose sensor comprising "receiving sensor data from a glucose sensor, including one or more sensor data points; receiving reference data from a reference glucose monitor, including one or more reference data points; providing one or more matched data pairs by matched reference glucose data to substantially time corresponding sensor data; forming a calibration set including at least one matched data pair; evaluating the quality of said calibration set based on data association; and *converting sensor data into calibrated data responsive to the quality of said calibration set*" (emphasis added).

In contrast to the pending claims, which relate to methods of prospectively processing sensor data or processing sensor data substantially in real time, Mastrototaro describes a method for *retrospectively* processing sensor data after it has been collected. For example, page S-13, col. 2 states "[d]ata are collected ... and can be periodically downloaded into a computer for analysis and interpretation." Similar disclosures are found on page S-14, col. 1, third full paragraph: "[t]he CGMS is used primarily by the health care professional to gather continuous glucose data on patients already diagnosed with diabetes mellitus. The data collected by the system, when downloaded to a PC, can be useful to the HCP in managing ..." Also, see page S-15, at the top of col. 1, which states "[a]fter wearing a sensor for up to 3 days, patients return to the medical office where the data from the CGMS is downloaded to a PC for review." The entire description of the evaluation of the data itself can be found in Mastrototaro under the header "FORMAT OF DATA DISPLAY FOR THE HEALTHCARE PROFESSIONAL," and only describes *retrospective* processing.

Accordingly, Applicants respectfully request that the rejection be withdrawn.

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Claim Rejection - 35 U.S.C. §103(a) – Mastrototaro

Claims 2, 3, 8-10, 21, 22, 27-29, 41, 42, and 46-48 have been rejected under 35 U.S.C. §103(a) as obvious over Mastrototaro. To establish a *prima facie* case of obviousness, three basic criteria must be met: first, the prior art reference (or references when combined) must teach or suggest all the claim limitations; second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; finally, there must be a reasonable expectation of success. *See* M.P.E.P. § 2143.

As discussed above, and in contrast to the pending claims which relate to methods of prospectively processing sensor data or processing sensor data substantially in real time, Mastrototaro only describes a method for *retrospectively* processing sensor data after it has been collected.

Accordingly, Mastrototaro neither teaches nor suggests all limitations of Applicants' pending claims. Applicants therefore respectfully request withdrawal of the rejection.

Claim Rejection - 35 U.S.C. §103(a) – Mastrototaro in view of Sato et al.

Claims 12-14, 31-33, and 50-52 have been rejected under 35 U.S.C. §103(a) as obvious over Mastrototaro in view of U.S. Publication No. 2003/0023171 ("Sato et al."). Sato et al. merely discloses use of a least squares regression to calculate a correlation coefficient. It includes no teaching or suggestion of prospectively processing sensor data or processing sensor data substantially in real time.

Because Sato et al. does not overcome the deficiencies of Mastrototaro, a *prima facie* case of obviousness cannot be made. Applicants therefore respectfully request withdrawal of the rejection.

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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